K112818

JUL 3 1 2012

July 12, 2012

510(k) SUMMARY

VIDAS® D-Dimer Exclusion II Assay

A. Submitter Information

Submitter's Name:	bioMérieux, Inc.
II. **Address:**	**595 Anglum Road** Hazelwood, MO 63042
Contact Person:	John Albright
Phone Number:	314-731-8546
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Date of Preparation:	September 2011

B. Device Name

Trade Name:	VIDAS® D-Dimer Exclusion II Assay
Common Name:	D-Dimer Exclusion II Assay
Classification Name:	21 CFR 864.7320 Product Code DAP Fibrinogen/fibrin degradation products assay

C. Predicate Device Name

Trade Name:	VIDAS® D-Dimer Exclusion Assay

D. Device Description

The VIDAS® D-Dimer Exclusion II assay is an automated quantitative test for use on the instruments of the VIDAS family for the determination of fibrin degradation products (FbDP) in human plasma (sodium citrate) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. VIDAS D-Dimer Exclusion II is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE.

The assay principle combines a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR), a pipette tip-like device, serves as the solid phase as well as the pipetting device for the assay. The assay reagents are ready-to-use and pre-dispensed in the sealed reagent strips (STRs). The individual kit components are described in detail on the following pages.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.

First, the sample is taken by the SPR, diluted and then cycled in and out of the SPR several times. The antigen binds to the anti-FbDP immunoglobulins coated on the SPR. Unbound components are eliminated during a washing step. In the second step, the conjugate that contains an alkaline phosphatase labeled anti-FbDP monoclonal antibody is cycled in and out of the SPR to form a sandwich. Unbound components are eliminated during the washing steps.

A detection step is then performed. The substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm. The intensity of fluorescence is proportional to the concentration of antigen present in the sample. At the end of the assay, results are automatically calculated by the instrument in relation to the calibration curve stored in memory. The results are then printed.

E. Intended Use

VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate, CTAD) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS D-Dimer Exclusion II is indicated for use in conjunction with a clinical pretest probability assessment model **to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE)** disease in outpatients suspected of DVT or PE.

F. Technological Characteristics Summary

A general comparison of the similarities and differences of the current assay, VIDAS D-Dimer Exclusion II (ref. 30445) and the predicate assay VIDAS D-Dimer Exclusion (K040882) ref. 30442 is presented in the table below.

III. Item	VIDAS® D-Dimer Exclusion II Assay	VIDAS® D-Dimer Exclusion Assay (K040882) - Predicate
General Comparison		
Intended Use	VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS D-Dimer Exclusion II is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE.	VIDAS D-Dimer Exclusion is an automated quantitative test for use on the VIDAS instruments for the Immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate) using the ELFA technique (Enzyme-Linked Fluorescent Assay). VIDAS D-Dimer Exclusion is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE.
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Enzyme-linked fluorescent assay (ELFA)
Automated	Yes	Yes
Assay Duration	19 minutes, 57 seconds	35 minutes, 35 seconds
SPR	Coating solution includes Anti-FbDP monoclonal mouse antibodies	Coating solution includes Anti-FbDP monoclonal mouse antibodies
	No preservative	Buffer preservative=azide
Strip	Conjugate includes alkaline phosphatase-labeled anti-FbDP monoclonal immunoglobulins (mouse)	Conjugate includes alkaline phosphatase-labeled anti-FbDP monoclonal immunoglobulins (mouse)
	MIT or MIT + BND (Wells 5-9 replaced sodium azide with MIT or MIT+ BND). Sodium azide only remains in well 10.	Preservative = azide (Wells 5-10 contain sodium azide as the preservative)
	Conjugate buffer contains Non specific Purified mouse IgG*	Conjugate buffer contains Non specific Mouse ascite Tg180
	Nonirradiated de-complemented horse serum	Conjugate buffer includes de-complimented irradiated or non irradiated horse serum
Calibrators and Controls Approximate target (ng/mL)	S1: 3000-3500 S2=N/A C1 : 5200-6040 C2 : 250-380	S1 : 3700-4400 S2 : 420-580 C1 : 4200-4800 C2 : 380-520
	Allows reconstitution with water	Reconstituted with the R1 diluent included in the kit
	Recalibration frequency=28 days	Recalibration frequency=14 days
Sample type	Citrated or CTAD plasma	Citrated plasma

G. Performance Data

A summary of the non-clinical results is presented in the table below.

Analytical Performance Comparison			
IV. Item	**VIDAS® D-Dimer Exclusion II Assay**		**VIDAS® D-Dimer Exclusion Assay (K040882) - Predicate**
Assay range	45-10,000 ng/mL		45-10,000 ng/mL
Clinical Cut Off	500 ng/mL		500 ng/mL
Linearity	45-10,000 ng/mL		45-5,000 ng/mL
Detection Limit	≤ 45 ng/mL		≤ 45 ng/mL
Hook Effect	400,000 ng/mL		400,000 ng/mL
Specificity	Fibrinogen (<10 g/L)	No cross reactivity	No cross reactivity for fibrinogen or fibrinogen degradation products X, Y and D
	Fibrinogen degradation products X (< 10 µg/mL)		
	Fibrinogen degradation products Y (<10 µg/mL)		
	Fibrinogen degradation products D (10 - 100 µg/mL)	Cross reactivity between 10-100 µg/mL; however such high levels of fibrinogen degradation products D do not occur in the target population of suspected VTE patients	
Total Precision (CV)	CV 6.6 % at 277.97 ng/mL CV 5.9 % at 544.14 ng/mL CV 6.0% at 7,788.88 ng/mL		CV 5.7 % at 264 ng/mL CV 5.8% at 549 ng/mL CV 7.1% at 7283 ng/mL
Interference	No interference with Hemoglobin up to 300 µmol/L Lipemia up to 30 g/L Bilirubinemia up to 537 µmol/L Rheumatoid factor: up to 400 IU/mL Human albumin: up to 60 g/L		No interference with Hemoglobin up to 300µmol/L Lipemia up to 20 g/L Bilirubin up to 537µmol/L Rheumatoid 396 IU/mL
Drug Interference	47 analytes were tested and no interference was observed		Not performed
Normal Values	90% less than 500 ng/mL		96% less than 500 ng/mL
Method Comparison	D-Dimer Exclusion (K040882) vs. D-Dimer Exclusion II.		N/A

H. Conclusion

The VIDAS® D-Dimer Exclusion II Assay is substantially equivalent to the bioMerieux VIDAS D-Dimer Exclusion Assay.

The 510(k) summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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bioMerieux, Inc.
c/o Ms. VeRonica Daenzer
Sr. Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, MO 63042-2320

JUL 3 1 2012

Re: k112818
Trade/Device Name: VIDAS® D-Dimer Exclusion II™ (DEX2)
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: Class II
Product Code: DAP
Dated: July 30, 2012
Received: July 31, 2012

Dear Ms Daenzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Leena Philip

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112818

Device Name: VIDAS® D-Dimer Exclusion II Assay

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In-Vitro Diagnostic Device
Evaluation and Safety

510(k) K112818